REMARKS/ARGUMENTS

Claims 1-31 were pending at the time of the mailing of the outstanding Office Action. Claims 16-25 and 30-31 have been withdrawn from consideration. By this amendment, claims 1, 3-6 and 10-11 have been amended. Claim 2 has been cancelled without prejudice or disclaimer as to the subject matter contained therein. Non-elected claims 30 and 31 have also been cancelled without prejudice or disclaimer. No claims have been added.

In the Office Action of 30 November 2005, claims 1, 2, 5-13, 26-29 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu"). Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu. Claims 14 and 15 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu in view of U.S. Pat. No. 6,287,628 to Hossainy et al. (hereinafter "Hossainy").

The Applicants continue to maintain that Wu does not anticipate or make obvious claims 1-15 and 26-29. The Examiner maintains that Wu discloses a stent having microdevices raised out from a base body to form microcannulae on the surface of the stent to penetrate into the vessel wall. The Examiner cites column 6, lines 13-17 of Wu in support of this interpretation. As the Applicants stated previously, this section of Wu only indicates that these microstructures ("craters 200") engage the passageway of the lumen of a blood vessel when the stent is deployed. No teaching or suggestion is made that these structures are "raised out of the implant surface to such an extent that … the microcannula penetrates into the media of the blood vessel" as recited in claim 1. Wu merely teaches that the "craters" "can be used to deliver therapeutic substances from the stent directly to the lumen wall…" (column 2, lines 60-62).

To further distinguish the present invention from that of Wu, claim 1 has been amended to recite that the microcannula(e) projects *from the surface* between about 100

and about 400 μm. This further distinguishes claim 1 from the teaching of Wu at column 11, lines 63-66 (as cited by the Examiner), where Wu provides that the depth (220) of the craters (200) is not measured from the surface of the structure as recited by claim 1, but from the bottom of crater 200 (see Fig. 2B of Wu). The depth 220 of Wu's craters may extend to as much as 100 μm (column 11, lines 65-66), but this distance is measured from the top of the lip 204 of the crater to the bottom surface 210 of the crater (column 5, lines 21-23) and includes arrangements where the bottom of the crater 210 is beneath the stent surface plane 114 as shown in Fig. 2B of Wu (see also column 5, lines 41-44). In contradistinction, the length of the microcannulae as now recited in claim 1 is measured from the surface of the stent. Wu does address the distance that craters 200 extend from the surface, but instead refers to this as lip height 218 (see again Fig. 2B of Wu). Wu discloses a lip height of only 10-80 μm (column 11, lines 65-67), not 100-400 μm as recited in claim 1.

This is distinction is significant because Wu provides a stent that includes structures that only allow delivery of a therapeutic substance directly to the wall of the vessel. Wu does not teach or suggest microcannulae that penetrate into the vessel wall. Wu merely provides that the protruding structures or craters "engage the lumen of the passageway ... to help prevent the stent from slipping out of the treatment site." Column 6, lines 15-17. Contrary to the Examiner's assertion, the Applicants did not admit in the previous response that the Wu device penetrates the vessel wall. To the contrary, the Applicants pointed out that Wu specifically indicates exactly the opposite: that Wu indicates that the craters 200 of their stent "engage the lumen of the passageway when the stent is deployed." Because the "lumen" of a blood vessel is actually the inner open space or cavity of the blood vessel, Wu can only mean that the craters 200 contact ("engage") the wall of the blood vessel at its surface.

Additionally, Wu's terminology (i.e. "craters") for these structures further indicates that Wu does not envision or intend for these structures to act as microcannulae penetrating into the media of the blood vessel as in the present invention. Rather, the

structures are merely intended to engage and secure the stent to a vessel or to a cover for the stent. Even assuming *arguendo*, that the craters of Wu had a sufficient height to act as microcannulae to deliver substances to the media of a blood vessel, Wu provides no indication that this height alone would be sufficient for these structures to act in this manner. As stated previously, Wu provides no teaching or suggestion that these craters penetrate into the vessel past the endothelium, the basal lamina, and the inner elastic membrane and allow delivery of such substances directly into the media.

Therefore, the Applicants maintain that Wu does not teach or suggest all of the elements of claim 1, namely, a stent having a microcannula that extends from the surface between about 100 and about 400 μm and that penetrates into the media of a blood vessel when the stent bears against the wall of the blood vessel. Therefore, claim 1 patentably distinguishes over Wu. Likewise, claims 5-13, and 26-29, which directly or indirectly depend from claim 1, and contain all the limitations of claim 1 also patentably distinguish over Wu. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claims 3 and 4 stand rejected as obvious over Wu. Claims 14 and 15 stand rejected as obvious over Wu in view of Hossainy. Neither Wu nor Hossainy, either independently or in combination, teach or suggest a stent having microcannulae that extend from the surface between about 100 and about 400 μm and that penetrate into the media of a blood vessel when the stent bears against the wall of the blood vessel, as detailed above. Additionally, one of ordinary skill in the art would not have found any suggestion or motivation to modify the length of the craters of Wu to 100-400 μm, or to 150-300 μm, or to 180-250 μm, or to any other length. Contrary to the Examiner's assertions, the Applicants have provided a distinct advantage of the claimed microcannula length ranges, namely, to deliver therapeutic products directly into the media of blood vessels, not just to the interior surface of the blood vessels. Neither Wu nor Hossainy provide any teaching or suggestion that such delivery is desirable or possible. Therefore, the Applicants maintain that claims 3, 4, 14, and 15 patentably

distinguish over Wu, either alone or in combination with Hossainy. Withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

Because the amendments presented herein place the claims under consideration in condition for allowance, entry of this Amendment after Final Rejeetion is appropriate. Furthermore, because claims 1, 3-11, 14, 15 and 26-29 are generic for all species within elected Invention I, rejoinder of non-elected claims 16-25 is hereby requested. Amendments to claims 3-6 and 10-11 introduce minor changes to make these claims consistent in their wording with amended claim 1. None of the amendments will necessitate an additional search. In the event that the Examiner disagrees with the Applicants regarding the allowability of the pending claims, entry of the Amendment should still be made on the grounds that amendment of claim 1 and cancellation of claims 2, 30 and 31 simplifies matters under consideration for appeal.

The outstanding Office action was mailed on 30 November 2005 and a response is timely if filed on or before 28 February 2006. No fees are believed to be due with the filing of this response. However, in the event that a fee for the filing of this response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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